UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF GEORGIA
ATHENS DIVISION

BASF AGRO B.V., MERIAL LIMITED and MERIAL SAS Plaintiffs, v. CIPLA LIMITED, *et al.* Defendants and VELCERA, INC. and FIDOPHARM, INC., Intervenors.	Case No. 3:07-CV-00125-CDL **PUBLIC VERSION**

INTERVENORS VELCERA, INC. AND FIDOPHARM, INC.'S REPLY MEMORANDUM IN SUPPORT OF MOTION FOR CLARIFICATION OF THE JUNE 21, 2011 PERMANENT INJUNCTION

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I. INTRODUCTION

Merial's Response to FidoPharm's Motion leaves no doubt that there is a ripe issue for this Court to decide—namely, whether the 2011 Injunction is so broad as to bar FidoPharm from selling under the PetArmor® Plus brand a new generic equivalent to Frontline Plus that FidoPharm developed after entry of the Order and independently of Cipla.

The new PetArmor® Plus product is:

- [redacted]
- manufactured by a company that is unrelated to Cipla [redacted];
- supported by entirely new data generated by third party contractors having no affiliation with Cipla.

In support of its Motion, FidoPharm provided uncontested evidence of all of the above, and it has promptly responded to Merial's post-Motion requests for information about the new formulation, including by disclosing the identities of the third parties involved in the testing and generation of data and the particular studies that each conducted. FidoPharm has also repeatedly offered to allow Merial's outside lawyers and a technical expert to have access to the details of the new formulation, subject to eminently reasonable confidentiality provisions. Tellingly, Merial has made the choice not to see the formulation details.

Merial will simply never be satisfied, and it will never acknowledge that FidoPharm is acting in compliance with the Order. Indeed, notwithstanding the Court's express statement that "[t]he Court intends to limit the specific injunctive relief against Velcera to ***its conduct in***

concert with Cipla" (DE 75 at 48, n.11) (emphasis added), and the undisputed evidence that Cipla has had nothing to do with FidoPharm's new product, Merial suggests that under the "Cipla participated in the development" language of the 2011 Injunction, FidoPharm can somehow be held in contempt if its new product is the same as or "not colorably different from" the original PetArmor® Plus formulation or other formulations that Cipla tested on FidoPharm's behalf. (Merial Br. at 10-11). Thus, there is a very real and important dispute for the Court to decide regarding the scope of the 2011 Injunction, and FidoPharm appropriately seeks clarification to avoid unwitting contempt.

Merial's expansive interpretation contravenes the language of the Order and is also flat wrong as a matter of law. The Court issued the 2011 Injunction based on a finding that FidoPharm, a non-party to the 2008 default judgment and injunction, aided and abetted Cipla's violation of the 2008 injunction. Merial never asserted in this case, much less proved, a claim against FidoPharm for patent infringement. Accordingly, under controlling Federal Circuit law ignored by Merial in its brief, the 2011 Injunction cannot restrain FidoPharm from engaging in future conduct independently of Cipla. The Court should reject Merial's interpretation and confirm as a matter of law that the 2011 Injunction restrains FidoPharm only to the extent it acts in concert with Cipla after entry of the Order to sell fipronil plus s-methoprene products. The Court should further hold, based on that proper interpretation and the uncontroverted facts, that FidoPharm's new PetArmor® Plus product, developed by FidoPharm independently of Cipla and manufactured by a third party with no relation to Cipla, is not covered by the 2011 Injunction.

II. ARGUMENT AND AUTHORITIES

A. The Court Should Clarify the Scope of the 2011 Injunction

In support of its argument that the Court should find FidoPharm in contempt of the 2008 injunction against Cipla, Merial took FidoPharm to task for not asking this Court before commercial launch of PetArmor® Plus to clarify whether that injunction applied to FidoPharm's activities with Cipla. (Stimart Decl., Ex. 2 at 311:20 – 312:4). Yet Merial now argues that by requesting clarification that the 2011 Injunction does not apply to FidoPharm's independent development of its new product, FidoPharm seeks an improper advisory opinion. The reason for Merial's expedient flip-flop is clear: Merial has no evidence or legal basis to oppose FidoPharm's Motion, but it wants the specter of a contempt proceeding to hang over FidoPharm and, ideally, derail the planned 2012 launch of the new PetArmor® Plus product. Merial's transparent anticompetitive tactics should not be countenanced. FidoPharm's Motion presents a concrete and critically important issue regarding the reach of the 2011 Injunction.

Merial builds its "advisory opinion" argument on the false premise that FidoPharm failed in its Motion to identify any portion of the Order that requires clarification. (Merial Br. at 1, 9). In its opening brief, FidoPharm repeatedly highlighted the "participated in the development" language of the Order (*see, e.g.*, Op. Br. at 1-4, 6-7, 10), and noted that Merial had previously argued to this Court that FidoPharm could not avoid the reach of the Order by using an alternative manufacturer to make "PetArmor Plus products, for which the Court found Cipla participated in the development and U.S. approval." (*Id.* at 6).

Knowing full well what portion of the Court's Order is at issue, Merial refers directly to the "participated in" language and argues that it needs no clarification: "if Cipla participated in

the development, manufacture, and/or packaging of Velcera's 'new' fipronil and methoprene-containing product, that product is subject to the June 2011 Order." (Merial Br. at 9). Merial's flippant assertion begs the critical question: What does it mean for Cipla to have "participated in the development" of the new PetArmor® Plus product? Particularly in light of the Court's statement in the Order that "[t]he Court intends to limit the specific injunctive relief against Velcera [FidoPharm] to its conduct in concert with Cipla" (DE 75 at 48, n.11), as well as controlling law limiting the reach of injunctions against non-parties based on "active concert" liability (*see supra* at Section II.B), FidoPharm believes that the "participated in the development" language cannot be met unless FidoPharm and Cipla actually collaborate on the development of the product at issue. Merial, however, clearly has a very different view. Notwithstanding the uncontested evidence that Cipla had no involvement in the development, evaluation or testing of the new PetArmor® Plus formulation, Merial nevertheless implies that FidoPharm can be held in contempt if its new product is "not colorably different from" the original PetArmor® Plus or other formulations previously tested by Cipla. (Merial Br. at 11).

There is thus a very real dispute regarding the meaning of the "participated in" language, and for FidoPharm the prompt resolution of that issue is vitally important to its 2012 business plan and operations. FidoPharm is committed to respecting the Court's Order and wishes to avoid engaging in unwitting contempt. Clarification from the Court is therefore needed to "add certainty to an implicated party's efforts to comply with the order and provide fair warning as to what future conduct may be found contemptuous." *N.A. Sales Co. v. Chapman Indus. Corp.*, 736 F.2d 854, 858 (2d Cir. 1984). *See also Schmidt v. Lessard*, 414 U.S. 473, 476 (1974) ("Since an injunctive order prohibits conduct under threat of judicial punishment, basic fairness requires that those enjoined receive explicit notice of precisely what conduct is outlawed."); *cf. Tom*

James Co. v. Morgan, 141 Fed. App'x. 894, 897-98 (11th Cir. 2005) (objections to lack of specificity of Rule 65(d) injunction deemed waived where party failed before contempt proceeding to complain to district court or seek to have injunction modified)); *Combs v. Ryan's Coal Co.*, 785 F.2d 970, 979 (11th Cir. 1986) (failure to seek clarification or modification of Rule 65(d) consent decree constituted waiver of objection on appeal)).

B. Merial's Interpretation of the 2011 Injunction Contravenes Controlling Law

By initiating contempt proceedings directed at its (non-party) competitor's product, Merial managed to avoid litigating a patent infringement case against PetArmor® Plus and putting its baseless patent at risk in the process. Yet Merial apparently views the Court's Order as if it were the virtual equivalent of a permanent injunction entered after a full adjudication of patent validity and infringement by FidoPharm, rather than a Rule 65(d) injunction based on a finding that FidoPharm ***assisted Cipla*** in Cipla's violation of the 2008 injunction that arose from a default judgment. Merial's position is directly contrary to controlling law.

As emphasized in FidoPharm's opening brief, a finding of active concert contempt liability against a non-party to an injunction cannot "justify granting injunctive relief against the non-party in its separate capacity." *Additive Controls & Measurement Sys. v. Flowdata Inc.*, 96 F.3d 1390, 1395-96 (Fed. Cir. 1996) ("*Adcon I*"). Accordingly, as a matter of law, the Court's Order cannot enjoin conduct by FidoPharm in its own capacity separate and apart from Cipla. *See id.* (contempt injunction predicated on Rule 65(d) must be limited to the defendant's conduct "solely as it relates to [its] activities in concert with an enjoined party") (citing *Chase Nat'l Bank v. City of Norwalk*, 291 U.S. 431, 436-37 (1934)).

Tellingly, Merial's brief is ***entirely silent*** on this dispositive point of law, and on the Court's statement in the Order that "[t]he Court intends to limit the specific injunctive relief

against Velcera to its conduct in concert with Cipla." (DE 75 at 48, n.11). Given Merial's legally flawed interpretation of the "participated in the development" language, FidoPharm is at a minimum entitled to a clarifying order that FidoPharm is not enjoined from selling a fipronil plus s-methoprene product where Cipla did not (i) contribute to the conception and development of the product's formulation; (ii) test or analyze the formulation; or (iii) generate any data to support any application by FidoPharm for regulatory approval of the product. *See Granny Goose Foods, Inc. v. Teamsters*, 415 U.S. 423, 444 (1974) ("basic principle built into [Federal Rule of Civil Procedure] 65 is that those against whom an injunction is issued should receive fair and precisely drawn notice of what the injunction actually prohibits.").

C. FidoPharm's New Product Is Outside the Scope of the 2011 Injunction

In addition to clarifying the scope of the "participated in the development" language, the Court should further hold that FidoPharm's new PetArmor® Plus product is not covered by the 2011 Injunction. In its bid to hold a contempt motion in its back pocket, Merial urges the Court not to rule on FidoPharm's Motion on the ground that FidoPharm has not disclosed the details of its new formulation (Merial Br. at 10), while at the same time implying that FidoPharm is engaged in a devious scheme to sell a product that "is the same as its Cipla-developed (and enjoined) product . . . ." (*Id.* at 7). Both contentions are utterly baseless.

First, FidoPharm has provided ample and uncontroverted evidence that Cipla has had nothing to do with the development, manufacture or packaging of FidoPharm's new product, and Merial has only itself to blame for the fact that its outside lawyers and technical experts have not seen the formulation details. Specifically:

- Dr. Petrick's declaration, which stands unrebutted, outlines the process by which FidoPharm independently identified and developed the new formulation, discloses the

identity of the new third party manufacturer, and unequivocally states that Cipla has had no involvement with the product. (DE 148-2, ¶¶ 3-4).

- A sworn declaration from a Cipla representative submitted herewith confirms that Cipla and its affiliates have had no involvement whatsoever with FidoPharm's new combination product. In fact, Cipla was not even aware of FidoPharm's efforts to develop, manufacture or package a new fipronil plus s-methoprene product until FidoPharm filed its Motion. (Declaration of Ramachandran Gopalakrishnan ¶ 3).
- FidoPharm promptly and in good faith responded to the requests for additional information made by Merial one week after the filing of the Motion, including by identifying the testing and manufacturing entities involved with FidoPharm's new formulation and the third-party studies submitted by FidoPharm to the EPA. (DE 157-9, DE 157-11, Exs. 8, 10 to Howell Declaration).[1]
- FidoPharm repeatedly offered to disclose under reasonable confidentiality restrictions the details of its new (and still secret) formulation and of the previous (and still secret) candidate formulations tested by Cipla before entry of the 2011 Injunction. (DE 157-11, DE 157-12, DE 157-15, Exs. 10, 11, 14 to Howell Declaration). Merial stubbornly refused on the ground that ***Merial employee*** Dr. Judy Jarecki-Black must also have access to FidoPharm's proprietary formulation information (DE 157-10, Ex. 9 to Howell Declaration at 2), even though FidoPharm offered to allow Merial's outside counsel of record and a technical expert to have access ***without prejudice to***

[1] After FidoPharm responded to Merial's requests, Merial dramatically expanded its fishing expedition to include demands for, *inter alia*, "all documents that relate to FidoPharm's prior development activities of fipronil and s-methoprene formulations" and all of FidoPharm's "regulatory filings with the EPA for the PetArmor® Plus product and the purportedly new product to show whether FidoPharm is relying on or has submitted to the EPA any data, information, or formulas obtained or submitted in connection with PetArmor Plus as part of its application for EPA registration of the purportedly new product." (DE 157-10, Ex. 9 to Howell Declaration).

Merial's position that Dr. Jarecki-Black should also have access. (DE 157-13, DE 157-15, Exs. 12 and 14 to Howell Declaration).

Had Merial's outside lawyers actually wanted to see the formulation details and provide them to a technical expert for review, they would have done so by now. Merial could have simply agreed to accept the information on an outside counsel's and expert's eyes only basis and simultaneously argued to the Court that Dr. Jarecki-Black should also have access. Instead, Merial made a tactical decision not to see the formulation information, so that it could seek to delay resolution of FidoPharm's Motion and commercial launch of the new product by disingenuously arguing that it is in the dark about the formulation.[2]

It is evident that Merial's assertion that Dr. Jarecki-Black must also be granted access is sheer pretext. Moreover, Merial has failed to show, and it cannot show, that its ability to respond to FidoPharm's Motion will be impeded if its in-house counsel does not have access to the makeup of the still-secret formulation for the new PetArmor® Plus product.[3] *See R.R. Donnelly & Sons Co. v. Quark, Inc.*, No. CIVA 06-032, 2007 WL 61885, at *1 (D. Del. Jan. 4, 2007). Further, Merial cannot be trusted to safeguard FidoPharm's confidential information about the new PetArmor® Plus product, as evidenced by its recent ***public filing in Delaware*** of two documents produced by FidoPharm in this case under a "Highly Confidential Attorneys' Eyes Only" designation. (*See* Stimart Decl., Ex. 3).

[2] In addition, in arguing for dismissal of FidoPharm's recent declaratory judgment action in Delaware, Merial claims, without acknowledging FidoPharm's repeated offers of access to the formulation details, that it cannot possibly accuse FidoPharm's new PetArmor Plus product of infringing the '329 patent without knowing the precise makeup of the product, notwithstanding that Merial did just that with respect to the original PetArmor® Plus before its commercial launch.

[3] Merial's argument that the formulation of the new product "may be easily determined" once it is commercially available (Merial Br. at 4) is specious. At present, FidoPharm's new product is not commercially available, and the precise makeup of the formulation remains a trade secret that does not belong in the hands of any Merial employee.

Second, Merial's suggestion that FidoPharm's new product is "the same as its Cipla-developed (and enjoined) product" is pure fiction. Having elected to remain ignorant of the formulation details, Merial grossly distorts a letter from the EPA approving the labeling for the new PetArmor® Plus product to imply that FidoPharm's representations to this Court about its independent development of a new formulation are false. [redacted] These are red herrings that have nothing to do with the fact that FidoPharm developed its new combination product after entry of the 2011 Injunction without any participation by Cipla.

[redacted] As Merial's own expert acknowledged, inactive ingredients can significantly affect product efficacy and aesthetics, and one must therefore be "judicious" in selecting the inactives for a pesticide formulation. (Stimart Decl., Ex. 2. at 86:20 – 88:21).

[4] Notwithstanding Merial's conscious decision to remain ignorant of the formulation details, to the extent the Court deems those details to be relevant to a determination of whether Cipla participated in the development of the new product, FidoPharm is certainly willing to disclose them under appropriate confidentiality restrictions so that the Court can see the differences between FidoPharm's new PetArmor® Plus product and the previous formulations tested by Cipla. FidoPharm submits that an *in camera* inspection of the formulation documents with outside counsel and one technical expert for each side present would be an appropriate and expeditious method at this point.

The product labeling documentation in the EPA file is also immaterial to whether Cipla "participated in the development" of FidoPharm's new product. EPA requirements dictate the information that must appear on a pesticide label, including identification of the active ingredients and their concentrations. (Supp. Petrick Decl. ¶ 6). [redacted] Merial's response is replete with spin and offensive innuendo, but it is entirely devoid of evidence that Cipla has had any involvement with FidoPharm's new PetArmor® Plus Product. FidoPharm's Motion should therefore be granted.

III. CONCLUSION

For the foregoing reasons, and for the reasons set forth in its opening brief, FidoPharm requests that the Court clarify the scope of the 2011 Injunction to confirm that FidoPharm's new fipronil and s-methoprene product, developed independently of Cipla and manufactured and packaged by an unrelated third-party manufacturer, falls outside the scope of the injunction.

[5] Similarly, the appearance of the old product's registration number in FidoPharm's application materials for the new PetArmor® Plus Product (Merial Br. at 7-8) is also irrelevant. Because a product registration for "PetArmor® Plus" already existed at the time that FidoPharm sought EPA approval for its new formulation, FidoPharm's submissions to the EPA for its proposed new formulation had to reference that existing registration number. (Supp. Petrick Decl. ¶ 4). With the subsequent regulatory approval of the new PetArmor® Plus product, FidoPharm can no longer manufacture the original PetArmor® Plus product for sale in the United States. (*Id.*).

Respectfully submitted this 6th day of February, 2012.

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CERTIFICATE OF SERVICE

I hereby certify that on this 6th day of February, 2012, the foregoing INTERVENORS VELCERA, INC. AND FIDOPHARM, INC.'S REPLY MEMORANDUM IN SUPPORT OF MOTION FOR CLARIFICATION OF THE JUNE 21, 2011 PERMANENT INJUNCTION was filed electronically with the Clerk of Court using the CM/ECF system, which will provide notification of this filing to all attorneys of record and was served by electronic mail to all counsel of record identified below:

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